

# Bloomberg

---

## Glaxo Said to Have Paid \$1 Billion Over Paxil Suits

By Jef Feeley and Trista Kelley - Jul 20, 2010

GlaxoSmithKline Plc has agreed to pay more than \$1 billion to resolve more than 800 cases alleging its Paxil antidepressant caused birth defects in some users' children, according to people familiar with the settlements.

The accords, which provide an average payout of more than \$1.2 million to families of affected children, leave more than 100 birth-defect cases pending, the people said. Officials of Glaxo, the U.K.'s biggest drugmaker, said July 15 they set aside \$2.4 billion to resolve litigation over Paxil and its Avandia diabetes drug.

"It looks as if this should be covered in the liabilities to be charged in the second-quarter numbers," Nick Turner, an analyst at Mirabaud Securities in London, said today in an interview. "If there are further liabilities to be disclosed in the third-quarter numbers, that would be very disappointing."

The birth-defect settlements bring to more than \$2 billion the amount Glaxo has agreed to pay to resolve a variety of Paxil-related suits, including claims it caused suicides or attempted suicides and addiction problems, the people said.

Glaxo officials confirmed yesterday they agreed to settle some Paxil birth-defect cases filed against the drugmaker. They refused to comment on the terms of the settlements.

"The company has agreed to these settlements, despite its litigation defenses, in order to avoid the costs, burdens and uncertainties of ongoing litigation," Sarah Alspach, a Glaxo spokeswoman, said in an e-mailed statement.

### \$11.7 Billion in Sales

"GSK believes it acted properly and responsibly in conducting its clinical trial program, in marketing the medicine, in monitoring its safety once it was approved for use and in updating pregnancy information in the medicine's label as new information became available," Alspach added.

Approved in 1992 for U.S. use, Paxil generated about 523 million pounds (\$793 million) in sales in 2009, or about 1.8 percent of Glaxo's total revenue. The company had \$11.7 billion in U.S. Paxil sales for nine years starting in 1997, according to documents made public last year in a Pennsylvania trial over birth-defect claims.

Chief Executive Officer Andrew Witty has moved to replace revenue lost to generic versions of drugs such as Paxil. The drugmaker said in May it plans to double revenue from India and China by 2015 as it cuts prices to match competitors in emerging markets.

#### Settled Cases

The \$2.4 billion charge Glaxo announced for Paxil and Avandia litigation "includes provisioning for settled cases" and those still outstanding, officials said in an e-mailed statement.

The charge "reflects the company's ongoing efforts to resolve certain long-standing legal cases," Dan Troy, the company's general counsel, said in the release. "This represents a substantial portion of GSK's outstanding litigation."

Alspach declined today to specify how much of the \$2.4 billion charge is devoted to resolving Paxil litigation and how much has been set aside to deal with Avandia lawsuits. She also declined to say how much of the reserve will be used to pay legal fees for both cases.

The company has agreed to pay more than \$500 million so far to settle suits alleging Avandia posed an increase risk of heart attacks and strokes in diabetics, people familiar with those accords said earlier this month.

#### Serious Cases

The \$1.25 million average recovery in the Paxil birth- defect cases reflects the seriousness of the injuries and the fact that many of cases involved children with heart defects, Carl Tobias, a professor at University of Richmond Law School who teaches classes on mass-tort law, said in an interview.

"I think the settlement size was influence by who was injured and the type of injuries," Tobias said.

The birth-defect settlements came after a Philadelphia jury ordered Glaxo in October to pay \$2.5 million in damages to the family of Lyam Kilker, a 3-year-old boy born with a heart defect after his mother took Paxil while pregnant.

In Kilker's case, jurors concluded Glaxo officials "negligently failed to warn" the doctor treating Lyam's mother about Paxil's risks and concluded the medicine was a "factual cause" of the child's heart defects. The panel declined to award punitive damages against the drugmaker.

During the Kilker trial, the family's lawyers made public internal Glaxo documents showing executives talked about burying negative studies about Paxil's links to birth defects and that its own scientists were alarmed by the rising number of children who had been affected by the drug in the womb. Many of the cases involved children with heart defects.

#### Estimate of Verdicts

After the verdict in Kilker's case, an analyst estimated the company may be facing more than \$1 billion in additional verdicts in the more than 600 birth-defect cases waiting to be tried in Pennsylvania.

"A liability totaling \$1.5 billion is possible," Savvas Neophytou, a Panmure Gordon analyst in London, wrote in a note to investors the day after the verdict. He still recommended buying Glaxo shares because the award was likely to be reduced on appeal.

The majority of the birth-defect suits filed in Philadelphia have been settled, including Kilker's case, the people familiar with the accords said. Sean P. Tracey, the attorney who represented Kilker's family in the case, declined to comment on the settlement.

#### Settled Cases

Other lawyers who have settled their Paxil cases include Mark Robinson and Karen Menzies, two Los Angeles-based attorneys, and Clayton Clark, a Houston-based plaintiffs' lawyer, the people said. Robinson and Menzies didn't return calls for comment. Clark declined to comment on the settlement of his more than 500 cases.

Attorneys who continue to press birth-defect claims against Glaxo include Houston litigators Andy Vickery and Ed Blizzard, the people said. Alspach noted yesterday that Glaxo is facing three birth-defect cases that are set for trial in Philadelphia in September.

Blizzard didn't return a call for comment. Vickery said he was preparing for one of the September trials and wouldn't comment on whether he'd had settlement talks with Glaxo.

The average \$1.25 million payout in the birth defect cases compares with \$2 million average settlements in about 150 suicide cases, the people said. Glaxo also paid an average of \$300,000 to resolve about 300 attempted suicide cases, they said.

### \$50,000 a Case

Glaxo also paid an average of about \$50,000 per case to resolve about 3,200 claims linking Paxil to addiction problems, the people said.

It also paid \$2.5 million to New York to resolve accusations the company withheld safety data about the antidepressant. The company, calling the claims unfounded, agreed to release safety studies on the medicine's effect on children.

In 2005, the company added a black-box warning to its Paxil label that the drug increased the risk of suicidal thoughts among adolescents, following a request by the U.S. Food and Drug Administration to do so.

In 2001, a jury in Cheyenne, Wyoming, ordered Glaxo to pay \$6.4 million to the relatives of a man who shot his family to death and then turned the gun on himself after taking Paxil. The case was settled while on appeal, according to Kevin Colgan, a Glaxo spokesman.

Glaxo fell 14.5 pence, or 1.2 percent, to close at 1,173.5 pence in London trading today. The shares have fallen 11 percent this year. Glaxo's American depositary receipts, each representing two ordinary shares, rose 12 cents to \$36.37 at 4:16 p.m. in New York Stock Exchange composite trading.

The Philadelphia birth-defect case was Kilker v. SmithKline Beecham Corp. dba GlaxoSmithKline, 07-001813, Court of Common Pleas, Philadelphia County, Pennsylvania (Philadelphia).

To contact the reporters on this story: Jef Feeley in Wilmington, Delaware, at [jfeeley@bloomberg.net](mailto:jfeeley@bloomberg.net); Trista Kelley in London at [tkelley2@bloomberg.net](mailto:tkelley2@bloomberg.net).

©2010 BLOOMBERG L.P. ALL RIGHTS RESERVED.